

# OFFICIAL GAZETTE

## GOVERNMENT OF GOA, DAMAN AND DIU

### GOVERNMENT OF GOA, DAMAN AND DIU

Law Department (Legal Advice)

#### Notification

7/1/80-LGL

The following Notification received from the Government of India, Department of Health, New Delhi, is hereby republished for general information of the public.

*R. V. Durbhatker*, Under Secretary (Law).

Panaji, 29th December, 1980.

#### (DEPARTMENT OF HEALTH)

#### Notification

*New Delhi, the 2nd April, 1980*

G.S.R. 430. — Whereas certain draft rules further to amend the Drugs and Cosmetics Rules, 1945, were published, as required by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), at pages 2216 to 2219 of the Gazette of India, Part II, Section 3, Sub-Section (i), dated the 23rd September, 1978 under the notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health) No. G.S.R. 1166 dated the 12th July, 1978 inviting objections and suggestion from all persons likely to be affected thereby, before the expiry of 90 days from the date on which the copies of the Official Gazette containing the said notification were made available to the public.

And whereas copies of the said Gazette were made available to the public on the 7th October, 1978;

And whereas the objections and suggestions received from the public on the said draft have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the said Act, the Central Government after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:—

1. (1) These rules may be called the Drugs and Cosmetics (1st Amendment) Rules, 1980.

(2) They shall come into force on the date of their publication in the Official Gazette.

(3) In the Drugs and Cosmetics Rules, 1945, for Schedule R, the following Schedule shall be substituted, namely:—

#### "SCHEDULE R

(See rule 125)

1. **Scope.**— This standard specifies the requirements for condoms made of rubber latex intended for single use.

2. **Description.**— Condoms consist of cylindrical rubber sheaths with one end open. The open end shall terminate with an integral rim. The closed end may have a receptacle. They may be supplied rolled and shall be free from tackiness and shall be capable of being unrolled readily.

3. **Materials.**— (1) Condoms shall be manufactured from good quality rubber latex and shall be free from embedded grit and shall be opaque or translucent prior to the application of dusting materials or lubricants.

(2) The rubber latex, colours used and any dusting materials or lubricants applied to the condoms shall neither contain nor liberate substances which are known to have toxic or other harmful effects under normal conditions of use. Any dusting material or lubricant or colour used shall not have deleterious effect on the condoms or be harmful to the users.

4. **Procedure for sampling during production.**— Specimens constituting the test samples shall be taken at random successively from each quantum of production that is, from the quantity produced from the same finished rubber latex and under the same processing and finishing conditions of manufacture and samples from each quantum shall be tested separately to ascertain conformity of quantum with the specified requirements in accordance with the tests described in this Schedule.

(2) (a) The number of samples drawn from each quantum shall be not less than 1 per cent of the number of condoms in each quantum.

(b) The number of samples drawn from each quantum shall be tested for air inflation test and water leakage test in accordance with the method described in this Schedule.

(c) The number of test samples 'N' and the number of rejected samples 'R' from a sequence of production quanta shall be recorded in a register. The cumulative total of test samples 'N' and the cumulative total of rejected 'R' from the test shall be recorded and the condoms shall be deemed to comply with the requirements if the cumulative total of rejected 'R' is not more than  $0.01N + 3\sqrt{0.01N}$ .

The following Table shows how this formula operates for a typical series of quanta:

TABLE  
Sampling of Condoms

Quantum No.	Size of Quantum	Number of test samples	Cumulative number tested (N)	Cumulative total of rejected (R) to be not more than
1	2	3	4	5
1	10,000	100	100	4
2	10,000	100	200	6
3	20,000	200	400	10

(3) Each unit of 100 test samples shall be distributed for the various tests as follows: —

- 50 for air inflation test; and
- 50 for water leakage test.

(4) Where the number of test samples is a multiple of 100 the distribution scale mentioned above shall be prorated.

(5) If the cumulative total of samples rejected exceeds the number of allowables at any point in the sequence of quanta, the quantum at which this occurs shall be liable to rejection. The assessment of quality of further production quanta shall include all previous test results starting from quantum number 1 and approval of production shall be in suspense until the condition required by the scheme is again fulfilled.

(6) At least one sample shall be taken at random from each production quantum not exceeding 10,000 condoms and shall satisfy all relevant requirements regarding dimensions as under paragraph 9.

(7) 30 samples shall be taken at random from each batch and subjected to various tests as detailed below: —

- 10 samples for Tensile Strength (before and after ageing)
- 10 Samples for Elongation at break (before and after ageing)
- 10 samples for Tension Set.

If any sample fails in the above tests, the entire batch shall be declared as not of standard quality.

5. Procedure or sampling and testing of finished products by a manufacturer: —

A. Air Inflation Test and Water Leakage Test:—

(1) Statistical sampling for quality control assessment of the finished product in respect of air inflation test and water leakage test shall be done

in accordance with the plan set out in Annexure—I to this Schedule.

(2) A test sample failing in any of the above tests is to be considered as defective. If the cumulative total of rejects 'R' is found to be equal to or greater than the number shown against 'R' in the Annexure-I, the batch or lot shall be declared as not of standard quality.

B. Dimensions. — At least 2 samples drawn from the lot or batch shall satisfy the requirements regarding Dimensions as under paragraph 9.

C. Tensile properties. — At least 15 samples drawn from the lot or batch shall satisfy the requirements of tensile properties as under paragraph 12.

6. Procedure for sampling and testing of condoms by a purchaser. —

A. Air Inflation Test and Water Leakage Test:—

(1) Statistical sampling of condoms by a purchaser for air inflation test and water leakage test shall be done in accordance with the plan set out in Annexure-II to this Schedule.

(2) A test sample failing in any of the above tests is to be considered as defective. If the cumulative total of rejects 'R' is found to be equal to or greater than the number shown against 'R' in the Annexure-II, the batch or lot shall be declared as not of standard quality.

B. Dimensions. — At least 2 samples drawn from the lot or batch shall satisfy the requirements regarding Dimensions as under paragraph 9.

C. Tensile properties. — At least 15 samples drawn from the lot or batch shall satisfy the requirements of Tensile properties as under paragraph 12.

7. Sampling plan for a Drugs Inspector. — (1)

Where an Inspector under the Drugs and Cosmetics Act, 1940, desires to take for test samples from the premises of a manufacturer or a distribution depot, 20 containers from each batch of production may be selected by him on a random basis and from each of these containers, five samples shall be taken. The 100 samples so selected shall be distributed for various tests as specified in paragraph 8. In case, the number of containers is less than 20, the number of samples to be taken from each containers shall be proportionately increased.

(2) Where an Inspector under the Drugs and Cosmetics Act, 1940 desires to take samples from a sales premises, he shall take 100 samples from each batch of production in accordance with the procedure specified in sub-paragraph (1).

8. Sampled condoms drawn under paragraph 7 shall be distributed for the various tests as follows: —

- 2 samples for thickness, length, width and weight;
- 40 samples for air inflation test;
- 40 samples for water leakage test; and

18 samples for tensile strength, elongation at break and tension set (3 of which may be kept in reserve).

The sample shall be declared as not of standard quality if — (i) the number of condoms found defective in the air inflation test and water leakage test exceeds 3; or (ii) the sample fails to conform to the requirements of Dimensions as under paragraph 9 or tensile properties as under paragraph 12.

**9. Dimensions.** — (1) The length when unrolled (excluding teat) shall be not less than 160 mm.

(2) The width of a condom, when laid flat and measured at any point between 70 mm. and 90 mm. from the open end shall be 50 mm  $\pm$  5 mm.

(3) The double-wall thickness of a condom, when measured at any point between 70 mm. and 90 mm. from the open end shall be not more than 0.14 mm.

*Note.* — 1. The double-wall thickness shall be determined with a suitable micrometer dial gauge graduated in intervals of 0.01 mm.

*Note.* — 2. Condoms shall, prior to the measurement of thickness, have the dusting powder or the lubricant or both removed by means of water or propan-2-01.

(4) The weight of a condom shall not exceed 1.6 gm.

**10. Air Inflation Test.** — (1) Condoms which are subjected to air inflation test shall be capable of being unrolled easily when such unrolling is done on a mandrel of 35 mm. diameter. Condoms not capable of being unrolled because of thickness shall be rejected and shall be counted towards cumulative total of rejects.

(2) Inflate the condom with air to a diameter of 150 mm. The inflated sample shall be examined for the presence of pin holes or foreign matter. No such defect shall be discernible. The examination of the inflated condom shall be completed within a minute. In case any foreign matter or any visual defect is observed in a condom during the air inflation test, the condom shall be subjected to the Water Leakage Test also and if it fails in the latter test, it shall be included in the cumulative total of rejects.

*Note.* — Pin holes within 50 mm. from the open end can be ignored.

(3) Samples subjected to air inflation test shall not be used for any other tests described in this Schedule.

**11. Water Leakage Test.** — (1) Fit the specimen on to the end of a suitable mount of about 45 mm. diameter. Ensure that the outer surface of the specimen is in a dry state. Pour into the condom 50 ml. of water, gently squeeze and examine the teat area for visual evidence of leakage. In case there is no leakage, pour additional 250 ml. of water making sure that outer surface is free from water. If necessary, outer surface can be gently wiped with cloth pad or blotting paper to remove accidentally spilt water. Suspend the filled condom with its open end upward for not less than 3 minutes. No water droplets are observed.

*Note.* — Pin-holes within 50 mm. from the open end can be ignored.

**12. Tensile Strength, Elongation at Break and Tension Set.** — (1) The average tensile strength, elongation at break and tension set of rubber, taken from the samples of condoms each calculated after excluding the lowest and highest of at least five test results shall conform to the following requirements, namely: —

Original	Maximum permissible variation from the original after accelerated ageing at 70 $\pm$ 1°C for 96 hours in an air oven.
(i) Tensile Strength 170 Kgs./Sq. cm minimum	+ 10 per cent — 30 per cent
(ii) Elongation at break 650 per cent minimum	+ 10 per cent — 15 per cent
(iii) Tension Set	

When rubber is stretched to 70 per cent of elongation at break, kept in this stretched condition for 10 minutes and allowed to recover for 10 minutes, 10 per cent is the maximum permissible variation.

(2) Tests to determine compliance of the material with the requirements of tensile strength and elongation at break shall be carried out in accordance with the appropriate methods described in Annexure-III and IV.

**13. Colour Fastness.** — Not less than 10 samples taken at random from each batch of coloured condoms shall pass the following test for colour fastness namely:—

Thoroughly wet inside and outside of the condoms with distilled water. Make no attempt to remove any dusting material or lubricant. Wrap the wet condom in white absorbent paper so that the largest possible surface area of the condom is in contact with the paper and seal the whole in a suitable container to prevent loss of moisture. Allow the container and its contents to stand for 16 hours to 24 hours at room temperature. After removing the absorbent paper from the container, examine it visually in natural day-light for any indication of staining. No part of the absorbent paper shall be stained. If there is any indication of staining of the absorbent paper by any colouring agent present in any of the condoms or any dusting material or lubricant, the entire batch shall be declared to be not of standard quality.

**14. Labelling, Packing and Storage.** — (1) The packing shall protect the condoms from contamination and mechanical damage. The smallest packing offered to the consumer shall bear a clear permanent marking with the following particulars: —

- (i) Manufacturer's name and address, and the trade name of the condoms, if any.
- (ii) Batch number.
- (iii) Date of manufacture (Month and year only).
- (iv) Date of expiry (Month and Year only) which shall not be more than 36 months from the date of manufacture.

(v) the words "For single use only".

(2) The condoms shall be stored in a cool dry place away from heat and direct sunlight.

### ANNEXURE I

(See paragraphs 4 and 5)

Sampling Plan for quality control of condoms at  
Manufacturer's Level

#### BATCH SIZE 35001 to 1.5 LAKHS

##### Single Sampling Plan

Sample Size 500 :	AQL — 1.0
	AC — 10
	R — 11

#### BATCH SIZE 1.5 LAKHS TO 5 LAKHS

##### Single Sampling Plan

Sample Size 800:	AQL — 1.0
	AC — 14
	R — 15

#### BATCH SIZE OVER 5 LAKHS

##### Single Sampling Plan

Sample Size 1250 :	AQL — 1.0
	AC — 21
	R — 22

Note: — AQL means Acceptance Quality Level.

AC means Acceptance Number i. e. the maximum allowable number of defectives for acceptance of the Batch.

R means Rejection Number i. e. the minimum number of defectives for rejection of the Batch.

### ANNEXURE II

(See paragraphs 6)

Sampling Plan for Quality Control of Condoms at  
Purchaser's Level

#### BATCH SIZE 35001 to 1.5 LAKHS

##### Single Sampling Plan

Sample Size 500 :	AQL — 1.5
	AC — 14
	R — 15

#### BATCH SIZE 1.5 LAKH TO 5 LAKHS

##### Single Sampling Plan

Sample Size 800 :	AQL — 1.5
	AC — 21
	R — 22

#### BATCH SIZE OVER 5 LAKHS

##### Single Sampling Plan

Sample Size 1250 :	AQL — 1.5
	AC — 21
	R — 22

Note: — AQL means Acceptance Quality Level.

AC means Acceptance Number i. e. the maximum allowable number of defectives for acceptance of the Batch.

R means Rejection Number i. e. the minimum number of defectives for rejection of the Batch.

### ANNEXURE III

(See paragraph 12)

Methods of Test for Determining Tensile Strength,  
Elongation at Break

**1. Principle of the Method.** — In the test, dumb-bell shaped test pieces are stretched in a tensile testing machine at a constant rate of traverse of the driven grip of pulley. Readings of load and elongation are taken as required during the uninterrupted stretching of the test piece and when it breaks.

**2. Apparatus.** — **Marker** — The marker for marking the reference lines on dumb-bell test pieces shall have two parallel knife edges. They shall be ground smooth and true. The distance between the centres of knife edges shall be  $25.0 \pm 0.1$  mm. The thickness of the lines shall be 0.05 to 0.08 mm.

**Tensile Test Machine.** — The machine shall be of such capacity that the maximum load required to break the test specimen shall be not more than 85 per cent and not less than 15 per cent of the rate capacity. The rate of traverse of the power actuated grip shall be 50.2 cm. and shall be uniform at all times. Possible separation of the grip of at least 75 cm. shall be provided. The machine shall be equipped with a scale or other device graduated to 1 mm for measuring the elongation, as shown by the distance between the gauge marks on the dumb-bell.

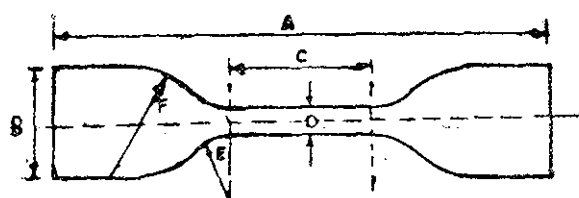
The machine shall be equipped with a type of grip which tightens automatically and exerts a uniform pressure across the gripping surfaces increasingly as the tension increases, so as to prevent uneven slipping and to favour failure of the specimen in its constricted section. It is advisable to have at the end of each grip a positioning device so that all specimens are inserted to the same depth in the jaws and are perpendicular to the direction of pull.

Note: — The machine shall be power-driven.

**3. Calibration of Tensile Test Machine.** — The load scale and the recording mechanism shall be calibrated at least once in three months to ensure that the load scale error does not exceed two per cent of the applied load.

**4. Preparation of Test piece.** — The test piece is dumb-bell shaped, which when punched with dies shall have the outline shown in figure below and

shall conform to the dimensions given in the following Table when read with the figure.



DUMB-BELL TEST PIECES

#### 5. Dimensions of Dumb-Bell Test Piece in mm. —

A: Overall length, minimum	115
B: Width of ends	$25 \pm 1$
C: Length of narrow parallel portion	$33 \pm 2$
D: Width of narrow parallel portion*	6.0 to 6.4
E: Small radius	$14 \pm 1$
F: Large radius	$25 \pm 2$

\*The variation within any one die should not exceed 0.05 mm.

**6. Measurement of Dumb-bell Test Pieces.** — Measure the thickness by a Micrometer, the foot of which exerts a pressure of 200 g/cm<sup>2</sup> on the rubber. The width of the test portion is assumed to be equal to the width between the cutting edge of the narrow central part of the die; for the purpose, the width of this part of the die is measured to the nearest 0.05 mm. Take the average of three measurements, one in the centre and two on each side.

**7. Conditioning of Test Pieces.** — The properties of vulcanized rubber change continuously with time, these changes being particularly rapid during the first twenty-four hours after vulcanization. Do not carry out any test within this period; for accurate comparisons between different rubbers it may be necessary to ensure that these are tested at substantially the same interval after vulcanization. Protest samples and test pieces as far as possible from light. Condition samples after any necessary preparation at the test temperature for not less than 12 hours immediately before testing.

**8. Temperature of test.** — Carry out the test at  $27 \pm 2^\circ\text{C}$ , unless otherwise specified.

**9. Determination of Tensile Strength and Elongation at break.** — Insert a dumb-bell test piece into the grips of the tensile testing machine taking care to adjust it symmetrically so that the tension is greater on one side of the test piece than on the other, the reference lines will not remain parallel and the maximum strength of the rubber will not be developed. Then start the machine and measure the distance between the centres of the reference lines as required to the nearest 1 mm, taking care to avoid parallax, until the test piece breaks. Note the load on the test piece as required.

Calculation of Results: —

**10. Tensile Strength.** — Calculate tensile strength by dividing the load at break by the initial area of cross-section of the test piece. Report the average tensile strength after excluding the lowest and highest of five test results. Note that the result of any

dumb-bell test piece which breaks outside the narrow part (reference lines) should be excluded.

**11. Elongation at Break.** — Calculate elongation at break by subtracting the initial distance between the reference lines on the dumb-bell test piece from the distance between the lines at breaking point and expressing the results as a percentage of the initial distance. Report the average elongation at break after excluding the lowest and highest of five test results. Note that the result of any dumb-bell test piece which breaks outside the narrow part should be excluded.

#### ANNEXURE IV

(See paragraph 12)

#### Method of Test for accelerated ageing

**Principle of the Method.** — The test consists in subjecting test pieces to controlled deterioration by air at an elevated temperature and at atmospheric pressure after which tensile strength and elongation at break are measured.

**2. Apparatus.** — The air oven shall be of such a size that the total volume of the test pieces does not exceed 10 per cent of the free air space of the oven. Provision shall be made for suspending test pieces so that they are not within 10 mm of each other or the sides of the oven. Provision shall be made for slow circulation of air in the oven of not less than three changes and not more than ten changes per hour. Care shall also be taken that the incoming air is heated to the temperature of the oven before coming into contact with the test pieces. The temperature of the oven shall be thermostatically controlled so that the test pieces are kept within  $\pm 1^\circ\text{C}$  of the specified ageing temperature. A thermometer shall be placed near the centre of the ageing test pieces to record the actual ageing temperature.

**Note:** — Copper or copper alloys shall not be used for the material of construction of the oven prescribed.

**3. Test piece.** — The form of the prepared test piece shall be such that no mechanical, chemical or heat treatment is required after ageing. Compare only test pieces of similar dimensions and having approximately the same exposed areas. Measure them before testing and mark them after the period of ageing is complete.

**4. Temperature of the oven.** — Maintain the oven at  $70^\circ \pm 1^\circ\text{C}$ .

**5. Duration of test.** — 96 hours.

**6. Procedure.** — Store all test pieces in the dark for a minimum period of 24 hours and a maximum period of 14 days prior to the commencement of the ageing period. See that the maximum temperature of storage before subjecting to an accelerated ageing test does not exceed  $30^\circ\text{C}$ . Carry out the testing of unaged test pieces within 14 days from the commencement of the ageing period. Place the test pieces in the oven after they have been preheated to the operating temperature. The test pieces are to be stationary, free from strain, freely exposed to air

on all sides and not exposed to light. When the ageing period is complete, remove the test pieces from the oven and store and condition for not less than 16 hours and not more than 96 hours in a strain-free condition and then condition in accordance with the details given in the appropriate test methods, for the particular physical property being studied."

[No. X-11013/5/77-D&MS]

G. PANCHAPAKESAN, Under Secy.

#### Notification

7/1/80-LGL

The following Notifications received from the Government of India, Ministry of Labour, New Delhi, are hereby republished for general information of the public.

B. S. Subbanna, Under Secretary (Law).

Panaji, 7th January, 1981.

#### GOVERNMENT OF INDIA

(BHARAT SARKAR)

#### MINISTRY OF LABOUR

(SHRAM MANTRALAYA)

New Delhi dated the 29th November, 1980.

#### Notification

G.S.R. 665 (E) — In exercise of the powers conferred by sub-section (1) of section 5, read with sub-section (1) of section 7 of the Employees' Provident Funds and Miscellaneous Provisions Act, 1952 (19 of 1952), the Central Government hereby makes

the following scheme further to amend the Employees' Provident Funds Scheme, 1952, namely :—

1. This Scheme may be called the Employees Provident Funds (Fifth Amendment) Scheme, 1980.

2. In the Employees' Provident Funds Scheme, 1952, in clause (b) of Sub-paragraph (3) of paragraph 1, after sub-clause (XCI) the following sub-clause shall be inserted, namely:—

"(XCII) as respects the Brick Industry, that is to say, any industry engaged in the manufacture of Bricks, specified in the notification of the Government of India in the Ministry of Labour No. G.S.R. 662(E), dated the 27-11-80, come into force on the 30th November, 1980."

[S-35016(5)/76-PF-II (ii)]

NAVIN CHAWLA

Deputy Secretary

Dated New Delhi, the 27th Nov., 1980

#### Notification

G. S. R. 662 (E) — Whereas the Central Government is of opinion that a provident fund scheme should be framed under the Employees' Provident Funds and Miscellaneous Provisions Act, 1952 (19 of 1952) in respect of the employees of the Brick Industry, that is to say, any industry engaged in the manufacture of Bricks;

Now, therefore, in exercise of the powers conferred by sub-section (1) of section 4 of the Employees' Provident Funds and Miscellaneous Provisions Act, 1952 (19 of 1952), the Central Government hereby adds with effect from the 30th November, 1980 the said industry to Schedule I of the said Act.

(No. S-35016(5)/76-PF-II)

NAVIN CHAWLA

Deputy Secretary